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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,836

10/20/2005

Hiroshi Fujita

053466-0444

6153

22428

7590

07/13/2009

FOLEY AND LARDNER LLP

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EXAMINER

GABEL, GALENE

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

07/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/553,836

Applicant(s)

FUJITA ET AL.

Examiner

GAILENE R. GABEL

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
4a) Of the above claim(s) 5-14 and 17-22 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-4, 15 and 16 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 20 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/20/05; 7/5/06; 6/28/07; 2/4/08; 9/9/08
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-4, 15 and 16, filed February 21, 2008 is acknowledged and has been entered. Claims 5-14 and 17-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 1-22 are pending. Claims 1-4, 15 and 16 are under examination.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4, 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 in the preamble is ambiguous in reciting, "the nature of horny layer oxidized protein" because it is unclear what is encompassed in the term "nature" as used in the claim. The term "nature" appears to be a subjective term that lacks a comparative basis for defining its metes and bounds.

Claim 1 is also vague and indefinite in reciting, "the method being characterized by comprising the steps of" because it is unclear how the recited method steps should be characterized." Does Applicant perhaps simply intend, "the method comprising"?

Claim 1 lacks clear antecedent basis in reciting, "the steps of specific fluorescent labeling" and "the carbonyl groups" because there does not appear to be a previously recited labeling step or carbonyl groups. Perhaps, Applicant intends, "specifically labeling carbonyl groups of ... with a fluorescent label."

Claim 1 is indefinite in reciting, "detection of the fluorescence for evaluation" because the term "detection" does not appear to recite an active method step and the recitation of "the fluorescence" lacks antecedent basis. Perhaps, Applicant intends, "detecting fluorescence signal from the fluorescent-labeled carbonyl groups to evaluate the horny layer oxidized protein."

Claim 2 has improper antecedent basis problem in reciting, "A method according to claim...." Perhaps, Applicant intends, "The method according to claim...". See also claims 3, 4, 15 and 16.

Claim 2 lacks clear antecedent basis in reciting, "the detection results." Additionally, it is unclear what is encompassed in reciting "detection results." Does Applicant perhaps intend, "wherein the fluorescent signal from the fluorescent-labeled

carbonyl groups on the horny layer oxidized protein is detected and imaged using a fluorescent microscope.”

Claim 3 is non-idiomatic and, therefore, confusing in reciting, “is accomplished by.” Perhaps, Applicant intends, “is performed by.”

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 4, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Thiele et al. (Macromolecular carbonyls in human stratum corneum: a biomarker for environmental oxidant exposure?, FEBS Letters 422: 403-406 (1998)).

Thiele et al. teach a method for evaluating horny layer oxidized protein. Thiele et al. provide that the presence of carbonyl groups in oxidized protein in the horny layer serves as intrinsic dosimeter for environmental oxidative damage (Abstract). In practice, the horny layer specimen (stratum corneum) is obtained by tape-stripping against the skin. The carbonyl groups present in the horny layer oxidized protein are specifically labeled by contacting the horny layer specimen with a hydrazine group containing fluorescent substance, i.e. carbonyl specific fluorescent label (2,4-dinitrophenyl hydrazine (DNPH) and rat anti-DNP), so as to allow the label to react with the carbonyl groups of the horny layer oxidized protein and create a fluorescent signal

(Abstract; p. 403, col. 2, 2nd full par. & 2.1 *Tape strippings*; p. 404, col. 1: 2.2 *ELISA assay of carbonyls*). Fluorescence of the reacted horny layer specimen having carbonyl groups that reacted with DNPH can be detected at appropriate wavelengths of emitted light (p. 404, col. 1).

In as far as the recitation of two-dimensional evaluation of the horny layer oxidized protein in the horny layer specimen in the preamble, such recitation has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 2 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thiele et al. (FEBS Letters 422: 403-406 (1998)) in view of Niwa et al. (Protein Oxidative Damage in the Stratum Corneum: evidence for a link between environmental oxidants and the changing prevalence and nature of atopic dermatitis in Japan, British Journal of Dermatology 149: 248-254 (January 2003)).

Thiele et al. is discussed supra. Thiele et al. differ from the instant invention in failing to teach detecting fluorescence from the horny layer oxidized protein using a fluorescent microscope to image the cells in the specimen and perform two-dimensional evaluation thereof.

Niwa et al. teach obtaining horny layer specimen from the skin (biopsy) and assessing the fluorescent signal obtained from reaction of DNPH with carbonyl groups of oxidized protein present in the horny layer by immunohistochemical detection (two-dimensional evaluation) using fluorescence microscopy. Niwa et al. found that positive staining of anti-DNP antibody is found in the most superficial layer of the stratum corneum (Abstract; p. 250, col. 2, 1st full par.; p. 251, col. 2, 1st full par.; and Figure 1).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to detect the reaction between carbonyl groups of oxidized protein in

the horny layer specimen in the method of Thiele, immunohistochemically by two dimensional evaluation using fluorescence microscopy as taught by Niwa because Thiele suggested use of DNPH as label having intrinsic fluorescence characteristic in specifically fluorescently labeling the carbonyl groups in the oxidative protein present in the horny layer, and Niwa specifically taught application and advantage of strong positive staining in using DNPH with immunohistochemical detection technique for two-dimensional evaluation of the horny layer oxidized protein.

6. No claims are allowed.

Remarks

7. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Thiele et al. (Protein Oxidation in Human Stratum: Susceptibility of Keratins to Oxidation, In Vitro and Presence of a Keratin Oxidation Gradient In Vivo (J. Invest. Dermatol. 113: 335-339 (1999)) teach employing an immunoblotting technique for detecting protein oxidation in corneum stratum obtained by tape-stripping (Abstract).

Yoshiki et al. (JP 11-344489, Abstract) teach transferring horny layer of skin cells to a double-sided tape attached to a face of a transparent plate, dyeing, and determining the cells using microscopy.

Chaudhuri et al., Oxidative Stress and Protein Carbonylations: A Fluorescence-based Approach, Free Radical Biology & Medicine, S102, Vol. 35, So. Supplement 1

(2003)) teach a fluorescence-based approach in detecting protein carbonyl groups in tissue which undergo oxidative stress.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAIENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

July 7, 2009